REMARKS

A. Objection to Claims

In the Office Action mailed on August 8, 2008, claims 1-31 were objected to for various informalities. In particular, claim 1 was objected to for using the phrase "monitoring one or more factors" instead of "monitoring of one or more factors." Applicants traverse the objection for the same reasons given in their Amendment filed on March 26, 2008 (hereinafter "the March 26, 2008 Amendment"). Despite the impropriety of the objection, the claim has been amended in the manner suggested by the Examiner. Accordingly, the objection should be withdrawn.

Claim 1 was also objected to for using the phrase "based on said automatically modifying said initial prescription" instead of "based on said automatic modification of said initial prescription." Applicants traverse the objection for the same reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objection, the claim has been amended in the manner suggested by the Examiner. Accordingly, the objection should be withdrawn.

Claims 12 and 13 were objected to for using the phrase "said automatically monitoring" instead of "said automatic monitoring." Applicants traverse the objections for the same reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objections, the claims have been amended in the manner suggested by the Examiner. Accordingly, the objections should be withdrawn.

Claim 17 was objected to because the phrase "automatically monitoring one or more factors, exclusive of a position of said area of interest, that could affect the effectiveness of said

automatically delivering said first dose of therapeutic radiation to said area of interest of said patient based on said diagnosis process" allegedly merged incomplete thoughts. Applicants traverse the objection because the phrase is clear in meaning for the reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objection, claim 17 has been amended in order to further clarify the claim. Since claim 17 is clear in meaning as amended, the objection should be withdrawn.

It is noted that the Examiner at page 2 of the Office Action has implied that the word "therapy" should be inserted after "said" in line 6. Assuming the Examiner's reference to line 6 refers to claim 17, it is unclear to which of the two instances of "said" in line 6 are being referred. Furthermore, the proposed insertion of "therapy" makes no sense there is no previous mention of "therapy" other than the preambles recitation of "active therapy redefinition." Since the insertion of "active therapy redefinition" after any of the occurrences of "said" make no sense, the Examiner's implication has no merit. Accordingly, Applicants request of this objection.

Claim 17 was also objected to for using the phrase "said automatically calculating" instead of "automatic calculation." Applicants traverse the objection because the phrase is clear in meaning for the reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objection, claim 17 has been amended in the manner suggested by the Examiner. Accordingly, the objection should be withdrawn.

Claim 21 was objected to for using the phrase "said automatically calculating" instead of

"said automatic calculation of." Applicants traverse the objection because the phrase is clear in meaning for the reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objection, claim 21 has been amended in the manner suggested by the Examiner. Accordingly, the objection should be withdrawn.

Claim 22 was objected to for using the phrase "said automatically performing" instead of "said automatic performance of." Applicants traverse the objection because the phrase is clear in meaning for the reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objection, claim 22 has been amended in the manner suggested by the Examiner. Accordingly, the objection should be withdrawn.

Claims 25-27 were objected to for using the phrase "said automatically monitoring" instead of "said automatic monitoring." Applicants traverse the objection because the phrase is clear in meaning for the reasons given in the March 26, 2008 Amendment. Despite the impropriety of the objections, claims 25-27 have been amended in the manner suggested by the Examiner. Accordingly, the objection should be withdrawn.

Note that the amendments to claims 1, 12, 13, 17, 21, 22 and 25-27 correct grammatical inconsistencies and/or clarify the invention claimed so that the intended meaning and scope of the claims are not altered. Accordingly, the amendments are not being made for reasons related to patentability as defined in *Festo Corporation v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000) (*en banc*), *overruled in part*, 535 U.S. 722 (2002).

B. 35 U.S.C. § 102

Claims 1-32 were rejected under 35 U.S.C. § 102(e) as being anticipated by Kapatoes et al. Applicants traverse the rejection. In particular, independent claims 1 and 17 recite "automatically monitoring one or more factors, exclusive of a position of said area of interest, that could affect the effectiveness of" either 1) "said initial prescription" (claim 1) or 2) "said automatically delivering said first dose" (claim 17). At page 3 of the Office Action, the Examiner appears to be asserting that the above mentioned processes of "automatically monitoring" are met by the monitoring of dosage and therapy received during the treatment as recited in column 7, lines 20-50 of Kapatoes et al. While the passage does mention computing intensity patterns of an image, such computation is necessarily dependent on using the position of the area of interest. Indeed, Kapatoes et al. is primarily concerned about how to direct radiation to a particular area based on geometrical factors. For example, see the discussion at column 6, lines 31-50 of Kapatoes et al on how the area of interest is of importance when computing dosage and intensity patterns of an image. Since Kapatoes et al.'s monitoring of factors depends on a position of an area of interest and claims 1 and 17 explicitly recite that the automatically monitored factor(s) are "exclusive of a position of said area of interest," claims 1 and 17 are not anticipated by Kapatoes et al.

The Examiner at page 5 of the Office Action has asserted that there is a logical fallacy created by Applicants interpretation of "exclusive of a position of said area of interest." The fallacy apparently is that in order to monitor a factor that could affect the effectiveness of an

initial prescription or automatically delivering a first dose, the position of the area of interest must be monitored. That is not necessarily true. As mentioned in paragraph 0048 at pages 19 and 20 of Applicants' Specification, the monitoring can include laboratory testing, stage of disease and stage of treatment. Such factors do not involve monitoring the position of the area of interest. As an example, suppose the area of interest is a lung that has cancer. According to the website MedicineNet.com (copy attached):

> Lung cancers frequently are accompanied by so-called paraneoplastic syndromes that result from production of hormone-like substances by the tumor cells. Paraneoplastic syndromes occur most commonly with SCLC but may be seen with any tumor type. A common paraneoplastic syndrome associated with SCLC is the production of a hormone called adrenocorticotrophic hormone (ACTH) by the cancer cells, leading to oversecretion of the hormone cortisol by the adrenal glands (Cushing's syndrome). The most frequent paraneoplastic syndrome seen with NSCLC is the production of a substance similar to parathyroid hormone, resulting in elevated levels of calcium in the bloodstream.

Based on the above MedicineNet.com statement, laboratory tests could be performed to see if the there has been an increase in the amount of adrenocorticotrophic hormone being produced by the patient since the last radiation treatment. If there has been an increase, the prescription plan can be adjusted accordingly.

As another example, monitoring the response to the use of the drug Gleevec for treatment of Gastrointestinal cancer could be applied to the invention. Laboratory testing regarding Gleevec could be used to indicate the need for more aggressive radiation treatment in a highlighted area rather than continuing chemotherapy. Other possible laboratory testing that could be applied to

the present invention that would not involve the position of an area of interest are tests that detect markers that could indicate hypoxia, proliferation, apoptosis or endothelial growth which implicates blood vessel creation. None of such markers are related to the position of an area of interest. Instead, their existence may suggest a change in course in treating a patient with radiation.

It is noted that the Examiner at pages 5 and 6 of the Office Action pointed out that Kapatoes et al. generates images of an area of interest at two points of time. The Examiner then asserted that such imaging "would fall under the cases of laboratory testing, physiological measurement, imaging and clinical observation. By reclassifying the imaging as being laboratory testing, physiological measurement, imaging and clinical observation, the Examiner is attempting to confuse the issue at hand. The fact remains, no matter how the imaging is classified, Kapatoes et al. is primarily concerned about how to direct radiation to a particular area based on geometrical factors as mentioned previously. In other words, Kapatoes et al. monitors the position of the area of interest.

The Examiner at page 6 of the Office Action has relied on the delivery verification and dose reconstruction processes described at column 3 of Kapatoes et al. as examples of monitoring factors that are exclusive of a position of an area of interest and could affect the effectiveness of the initial prescription. Instead of disclosing the recited monitoring, the delivery verification and dose reconstruction of Kapatoes et al. highlight a key difference in the claimed invention and Kapatoes et al. In particular, Kapatoes et al. is directed to

only monitoring the physical delivery of dose and recording what dose is delivered where. Kapatoes et al. implicitly assumes the original prescription is correct and so there is no need to change the original prescription. Instead, Kapatoes et al. modifies the original prescription to take into account a change in the area of interest. One of ordinary skill in the art would recognize that such modification is not the same as the modification of a treatment plan recited in the claims. Furthermore, since the modification of Kapatoes et al. is based on determining changes in the position/size of the tumor, Kapatoes et al.'s monitoring is based on the position of the area of interest. In contrast, the inventions of claims 1 and 17 recite using the monitoring to modify a treatment plan and such monitoring is exclusive of the position of an area of interest.

Claims 2-16 and 18-31 depend directly or indirectly on claim 1 or claim 17 and so their rejections are improper for at least the same reasons as stated above with respect to claim 1. The rejections of claims 4-6 and 11 are improper for the additional reason that Kapatoes et al. does not disclose the recited factors of: 1) anatomical and physiological variations within the area of interest (claim 4), 2) a stage of disease within the area of interest (claim 5), 3) a stage of treatment of the area of interest (claim 6) and 4) changes in applying the first and second therapeutic applications due to unscheduled breaks in the method of treatment (claim 11). It is noted that the Examiner at pages 5, line 19 to page 6, line 5 of the Office Action appears to be relying on the mere imaging of an area of interest at two different points in time as being by itself as being monitoring of stages of disease, anatomical and physiological variations and stages of disease. This is not true. Indeed, the passage at page 6, line 2 states that the above mentioned

monitoring "is inherently capable of being performed." Being inherently capable of performing a function is not anticipation under the law. The recited monitoring must be disclosed in Kapatoes et al. Since it is not, the rejection is improper and should be withdrawn. It is noted that the Examiner has still not identified one passage of Kapatoes et al. as anticipating claim 11.

The rejections of claims 8-10 and 25-27 are improper for the additional reason that Kapatoes et al. does not disclose the recited monitoring of: 1) laboratory testing of the patient (claims 8 and 25), 2) physiological measurement of the patient (claims 9 and 26) and 3) clinical observation of the patient (claims 10 and 27). It is noted that the Examiner at pages 5, lines 19-21 of the Office Action appears to be relying on the mere imaging of an area of interest at two different points in time as being by itself as being laboratory testing, physiological measurement and clinical observation. That is not the case. The fact is that Kapatoes et al. is silent as to laboratory testing, physiological measurement and clinical observation and so the claims are not anticipated by Kapatoes et al.

The rejections of claim 18, 20 and 21are also improper because Kapatoes et al. fails to disclose either 1) analyzing relevant information regarding a disease state and a condition of the patient (claim 18) or 2) performing decisions concerning the type and extent of disease (claims 20 and 21). It is noted that the Examiner has still not identified one passage of Kapatoes et al. as anticipating claims 18, 20 and 21.

The rejection of claim 30 is improper because Kapatoes et al. does not disclose the recited "automatically modifying a position of said patient based on said comparing." It is noted that the

Examiner has still not identified one passage of Kapatoes et al. as anticipating claim 30.

The rejection of claim 32 is improper because Kapatoes et al. does not disclose automatically monitoring one of: 1) anatomical and physiological variations within said area of interest, 2) a stage of disease within said area of interest; 3) a stage of treatment of said area of interest or 4) changes in applying said first and second therapeutic applications due to unscheduled breaks in said method of treatment." The previous comments regarding claims 4-6 and 11 are applicable.

CONCLUSION

In view of the arguments above, Applicants respectfully submit that all of the pending claims 1-32 are in condition for allowance and seek an early allowance thereof. If for any reason, the Examiner is unable to allow the application in the next Office Action and believes that an interview would be helpful to resolve any remaining issues, he is respectfully requested to con tact the undersigned attorneys at (312) 321-4200.

Date:

Respectfully submitted,

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